FEB 10 2012

K112016

8.0 510(k) Summary (as per 21 CFR 807.92)

I. GENERAL INFORMATION

Device Generic Name:	Infrared Lamp
Trade Name:	L-SER-KO IR Lamp
Device Classification:	Class II, Performance Standards 21CFR Part 890.5500 – Infrared Lamp
Product Code:	ILY
Applicant Name and Address:	YA-MAN LTD Shingu Bldg. 4F, 2-4-2 Toyo Koto-Ku, Tokyo 135-0016 Japan
510(k) Number:	Pending

II. DEVICE DESCRIPTION

The L-SER-KO IR Lamp (Figure 8.0) is intended for use as an infrared heat lamp. The L-SER-KO IR Lamp is a non-invasive device that emits light energy to the skin surface of the human body for the purpose of causing the therapeutic elevation of tissue temperature.

The L-SER-KO IR Lamp delivers an invisible laser beam in the infrared spectrum at wavelengths of 810 nm using a gallium aluminum arsenide (GaAlAs) source. The laser beam is generated by an IR diode. The tissue to be treated is illuminated by non-therapeutic red LED guide lights.

Figure 8.0 L-SER-KO IR Lamp

The L-SER-KO IR Lamp consists of only one hardware component, a handpiece containing the controller, user interface display and the treatment aperture.

The handpiece is made of standard medical PVC material.

III. INDICATIONS FOR USE

The L-SER-KO IR Lamp is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm; the temporary increase in local blood circulation; and/or the temporary relaxation of muscle.

IV. Predicate Devices

The L-SER-KO IR Lamp is substantially equivalent to other infrared therapeutic lamps that are currently in commercial distribution. These predicate devices include, but are not limited to, the USA Laser Biotech Inc. LUMINA 1600 Infrared Lamp Therapy System (K052814), and Avicenna ALT Laser Model VTR 75 (K031612).

Table 8.0 Predicate Comparison Chart

Characteristic	L-SER-KO IR Lamp	Lumina 1600 IR Heat Lamp System	Avicenna ALT Laser Model VTR 75
Manufacturer	YA-MAN LTD	Fisioline S.n.c, di Battagliotti	Avicenna Laser Technology, Inc.
510k Accession Number	Pending	K052814	K031612
Power Supply	115V single-phase 50-60 Hz	120V 50 – 60 Hz	120V 50-60 Hz
Heat Source	GaAlAs diode	GaAlAs diode	GaAlAs diode
Wavelength	665/810 nm	665/808 nm	660/980 nm
Average Power Output	1.2 W	1.6 W	1.0 – 7.5 W
Treatment Mode	Modulated	Modulated	Modulated
Treatment Times	Variable	Variable	Variable
Delivery System	Diode	Fiberoptic cable / handheld probe	Fiberoptic cable / handheld probe

V. Summary of the Technical Characteristics of the L-SER-KO IR Lamp as Related to the Referenced Predicate Devices.

The L-SER-KO IR Lamp and the aforementioned predicate devices are infrared lamps as defined in 21 CFR 890.5500. These devices utilize infrared light sources to generate topical heating for the purpose of

elevating tissue temperatures for temporary relief of muscle and joint pain.

VI. Testing

Testing of the L-SER-KO IR Lamp includes functional performance testing and electrical safety testing. The L-SER-KO IR Lamp is manufactured to comply with the following international standards:

- 21 CFR 1010 – Performance Standard for Electronic Products, General
- 21 CFR 1040 – Performance for Light-emitting Products
- EN 60601-1:2001 Medical Electrical Equipment, Part 1, General Requirements for Safety
- EN 60601-1-2:2001 Medical Electrical Equipment, General Requirement for Safety. Electromagnetic Compatibility
- ISO 14971 Medical Devices: Application of Risk Management

VII. Conclusions

Pursuant to the testing and comparison to the predicate devices, the L-SER-KO IR Lamp has the same intended uses, with similar functional and performance characteristics. The L-SER-KO IR Lamp is designed to comply with applicable performance standards promulgated by Federal Food and Drug Administration. The L-SER-KO IR Lamp performs as intended and does not raise any new safety or efficacy issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB 10 2012

Ya-Man Ltd.
% Clinical Technologies Research
Nelson Marquina, Ph.D.
9210 Forest Hill Avenue, Suite B3
Richmond, Virginia 23235

Re: K112016
Trade/Device Name: L-Ser-Ko IR Lamp
Regulation Number: 21 CFR 890.5740
Regulation Name: Powered heating pad
Regulatory Class: Class II
Product Code: ILY
Dated: February 04, 2012
Received: February 06, 2012

Dear Dr. Marquina:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

7.0 Indications for Use Statement

510(k) Number: **Pending** K112016

Device Name: **L-SER-KO IR Lamp**

Indications for Use:

The L-SER-KO IR Lamp is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm; the temporary increase in local blood circulation; and/or the temporary relaxation of muscle.

Prescription Use: X **AND/OR Over the Counter Use:** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODpE)

Neil R. Ogden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112016